Appln. No.: 10/766,631 J&J-106US

Amendment Dated December 9, 2008

<u>Amendments to the Claims:</u> This listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of Claims:

1. (Previously Presented) An aqueous formulation consisting essentially of, on a gram per 100 ml (reported as %) basis: 1-2 % 2,6-diisopropylphenol; water; and up to 15% excipients, wherein said excipients consist essentially of between about 2% and about 6% polyethylene glycol (PEG), from about 5% to about 9% poloxamer 188, and optionally, one or more pH modifiers, stabilizers, or tonicity modifiers, and wherein said formulation is an aqueous solution including less than 1% lipids and being clear to the naked eye.

2-11. (Canceled)

12. (Previously Presented) The formulation of claim 1, wherein the total amount of said poloxamer 188 is about 6% to 8% of said formulation.

13-19. (Canceled)

20. (Previously Presented) The formulation of claim 1, wherein the amount of 2,6-diisopropylphenol is about 1% of said formulation.

21-22. (Canceled)

- 23. (Previously Presented) The formulation of claim 1, wherein the total amount of PEG is less than 5% of said formulation.
- 24. (Canceled)
- 25. (**Currently Amended**) The formulation of claim $\frac{24}{1}$ wherein the PEG is between 2% and 4% of said formulation.
- 26. (Previously Presented) The formulation of claim 1, wherein the total amount of PEG is between 3 and 4% of said formulation.
- 27. (Previously Presented) The formulation of claim 1, wherein said PEG is selected from the group consisting of PEG-300, PEG-400, PEG-600, PEG-800, and PEG-1000.
- 28. (Previously Presented) The formulation of claim 27, wherein said PEG is PEG-400.

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29. (Previously Presented) The formulation of claim 1, wherein said excipients include propylene glycol and said propylene glycol is not more than 5% of said formulation.

- 30. (Previously Presented) The formulation of claim 29, wherein the amount of propylene glycol is not more than 2% of said formulation.
- 31. (Previously Presented) The formulation of claim 30, wherein the amount of propylene glycol is 1% to 2% of said formulation.
- 32. (Previously Presented) The formulation of claim 1, wherein said excipients include citric acid or a salt thereof.
- 33. (Previously Presented) The formulation of claim 32, wherein the concentration of said citric acid is in the range of from 2.5 to 15 mM.
- 34. (Previously Presented) The formulation of claim 32, wherein said formulation comprises citric acid in an amount of about 2 mg/ml.
- 35. (Previously Presented) The formulation of claim 1, wherein said excipients include an antimicrobial agent.
- 36. (Previously Presented) The formulation of claim 35, wherein said antimicrobial agent is selected from the group consisting of disodium edetate, metabisulfate, benzyl alcohol, cysteine or a salt thereof, and EDTA.
- 37. (Previously Presented) The formulation of claim 36, wherein said antimicrobial agent is benzyl alcohol in an amount of up to 0.5% of said formulation.
- 38. (Canceled)
- 39. (Previously Presented) The formulation of claim 28, wherein poloxamer 188 is present in an amount between 6 and 8% of said formulation; PEG-400 is present in an amount between 2 and 4% of said formulation; and the excipients include propylene glycol in an amount not greater than 2% of said formulation.
- 40. (Previously Presented) The formulation of claim 28, wherein poloxamer 188 is present in an amount of about 8% of said formulation; PEG-400 is present in an amount of about 4% of said formulation; propylene glycol is present as an excipient in an amount of about 1% of said

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formulation; and 2,6-diisopropylphenol is present in an amount of about 1% of said formulation.

- 41. (Previously Presented) The formulation of claim 28, wherein poloxamer 188 is present in an amount of about 8% of said formulation; PEG-400 is present in an amount of about 3% of said formulation; propylene glycol is present as an excipient and in an amount of about 1% of said formulation; and 2,6-diisopropylphenol is present in an amount of about 1%-of said formulation.
- 42. (Previously Presented) The formulation of claim 28, wherein poloxamer 188 is present in an amount of about 7% of said formulation; PEG-400 is present in an amount of about 4% of said formulation; propylene glycol is present as an excipient in an amount of about 1% of said formulation; and 2,6-diisopropylphenol is present in an amount of about 1% of said formulation.
- 43. (Previously Presented) The formulation of claim 28, wherein poloxamer 188 is present in an amount of about 7% of said formulation; PEG-400 is present in an amount of about 3% of said formulation; propylene glycol is present, as an excipient, in an amount of about 1% of said formulation; and 2,6-diisopropylphenol is present in an amount of about 1%-of said formulation.
- 44. (Previously Presented) The formulation of claim 28, wherein poloxamer 188 is present in an amount of about 6% of said formulation; PEG-400 is present in an amount of about 4% of said formulation; propylene glycol is present, as an excipient, in an amount of about 1% of said formulation; and 2,6-diisopropylphenol is present in an amount of about 1%-of said formulation.
- 45. (Previously Presented) The formulation of claim 28, wherein poloxamer 188 is present in an amount of about 6% of said formulation; PEG-400 is present in an amount of about 4% of said formulation; propylene glycol is present, as an excipient, in an amount of about 2% of said formulation; and 2,6-diisopropylphenol is present in an amount of about 1%-of said formulation.
- 46. (Previously Presented) The formulation of claim 28, wherein poloxamer 188 is present in an amount of about 6% of said formulation; PEG-400 is present in an amount of about 6% of said formulation; propylene glycol is present, as an excipient, in an amount of about 1% of said

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formulation; and 2,6-diisopropylphenol is present in an amount of about 1%-of said formulation.

- 47. (Previously Presented) The formulation of claim 28, wherein poloxamer 188 is present in an amount of about 8% of said formulation; PEG-400 is present in an amount of about 2% of said formulation; propylene glycol is present, as an excipient, in an amount of about 1% of said formulation; and 2,6-diisopropylphenol is present in an amount of about 1%-of said formulation.
- 48. (Previously Presented) The formulation of claim 28, wherein poloxamer 188 is present in an amount of about 7% of said formulation; PEG-400 is present in an amount of about 2% of said formulation; propylene glycol is present, as an excipient, in an amount of about 1% of said formulation; and 2,6-diisopropylphenol is present in an amount of about 1%- of said formulation.
- 49. (Previously Presented) An aqueous formulation consisting essentially of, on a gram per 100 ml (hereafter %) total formulation basis:
- a. 2,6-diisopropylphenol;
- b. water, and
- c. up to 15% excipients, wherein said excipients consist essentially of poloxamer 188 in an amount of at least 5% but less than 10% of said formulation, a polyethylene glycol in an amount of between 2% and 4% of said formulation, and optionally, one or more pH modifiers, stabilizers, or tonicity modifiers, and wherein the formulation includes less than 1% lipids and the formulation includes no other glycol or alcohol and is clear to the naked eye.
- 50. (Previously Presented) The formulation of claim 49, wherein said poloxamer 188 is present in an amount of between 5% to 9% (w/v) of said formulation; and said polyethylene glycol is PEG-400, present in an amount of between 2% and 4% (w/v) of said formulation.
- 51. (Previously Presented) The formulation of claim 50, wherein said poloxamer 188 is present in an amount of about 8% (w/v) of said formulation; PEG-400 is present in an amount of about 4% (w/v) of said formulation; and 2,6-diisopropylphenol in an amount of about 1% (w/v) of said formulation, wherein said formulation is substantially free of propylene glycol.

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52. (Previously Presented) The formulation of claim 50, wherein said poloxamer 188 is present in an amount of about 8% of said formulation; PEG-400 is present in an amount of about 3% of said formulation; and 2,6-diisopropylphenol is present in an amount of about 1% of said formulation, wherein said formulation is substantially free of propylene glycol.

- 53. (Previously Presented) The formulation of claim 50, wherein said poloxamer 188 is present in an amount of about 7% of said formulation; PEG-400 is present in an amount of about 4% of said formulation; and 2,6-diisopropylphenol is present in an amount of about 1% of said formulation, wherein said formulation is substantially free of propylene glycol.
- 54. (Previously Presented) The formulation of claim 50, wherein said poloxamer 188 is present in an amount of about 7% of said formulation; PEG-400 is present in an amount of about 3% of said formulation; and 2,6-diisopropylphenol is present in an amount of about 1% of said formulation, wherein said formulation is substantially free of propylene glycol.
- 55. (Previously Presented) The formulation of claim 50, wherein said poloxamer 188 is present in an amount of about 9% of said formulation; PEG-400 is present in an amount of about 2% of said formulation; and 2,6-diisopropylphenol is present in an amount of about 1% of said formulation.
- 56. (Previously Presented) The formulation of claim 50, wherein said poloxamer 188 is present in an amount of 8% of said formulation; and PEG-400 is present in an amount of 2% of said formulation.
- 57. (Previously Presented) The formulation of claim 50, wherein said poloxamer 188 is present in an amount of 7% of said formulation; and PEG-400 is present in an amount of 2% of said formulation.
- 58. (Previously Presented) The formulation of claim 49, further comprising, in the excipient portion thereof, citric acid or a salt thereof.
- 59. (Previously Presented) The formulation of claim 58, wherein said citric acid is at a concentration between 2.5 and 10 mM.
- 60. (Previously Presented) The formulation of claim 49, further comprising, in the excipient portion thereof, an antimicrobial agent.

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61. (Previously Presented) The formulation of claim 60, where said antimicrobial agent is benzyl alcohol.

- 62. (Previously Presented) The formulation of claim 1 or claim 49, wherein said formulation further comprises, in the excipient portion thereof, polysorbate.
- 63. (Previously Presented) The formulation of claim 62, further including in the excipient portion thereof, polyoxyethylene 20 sorbitan monooleate in an amount of 0.5 to 15 percent of said formulation; propylene glycol in an amount of 0.5 to 15 percent of said formulation; PEG-400 in an amount of 1 to 20 percent of said formulation; and poloxamer 188 in an amount of 2 to 15 percent of said formulation.
- 64. (Previously Presented) The composition of claim 1 or claim 49, wherein said poloxamer 188 is purified poloxamer 188, wherein said purified poloxamer has a polydispersity value of between 5 and 1, 4 and 1, 3 and 1, 2 and 1, or 1.1 and 1.
- 65. (Canceled)
- 66. (Previously Presented) An aqueous formulation, consisting essentially of, on a gram per 100 ml (reported as %) total formulation basis:
- a) a block copolymer in an amount of at least 5% but less than 10% of said formulation;
- b) a polyethylene glycol in an amount of between 2% and 6% of said formulation;
- c) 2,6-diisopropylphenol;
- d) water;
- e) optionally citric acid or a salt thereof; and
- f) optionally an antimicrobial agent

said components a, b, e, and f comprising excipients of said formulation, said excipients, in total, not exceeding 15% of said formulation, said formulation not exceeding 1% lipids and being clear to the naked eye.

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67. (Previously Presented) The formulation of claim 66, wherein said citric acid or a salt thereof comprises citric acid.

68. (Previously Presented) The formulation of claim 66, wherein the excipients of said formulation include an antimicrobial agent.

69-70. (Canceled)

71. (Currently Amended) A microemulsion, consisting essentially of:

- a) poloxamer 188;
- b) a polyethylene glycol (PEG);
- c) 2,6-diisopropylphenol;
- d) propylene glycol; and
- e) water,

said components a, b, and d comprising excipients and said excipients not exceeding 15[[%]] grams per 100 ml of said formulation, said microemulsion comprising less than 1% lipid and being clear to the naked eye.

- 72. (Previously Presented) An aqueous formulation, consisting essentially of (on a weight/volume grams/100 ml % basis):
- a) poloxamer 188 in an amount of at least 5% but less than 10% of said formulation;
- b) a polyethylene glycol in an amount of between 2% and 4% of said formulation;
- c) 2,6-diisopropylphenol; and
- d) water;

said components a and b comprising no more than 15% of said formulation, wherein said formulation has an average particle size of less than about 65 nanometers.

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73. (Previously Presented) A method of inducing or maintaining anesthesia in a mammal, comprising administering to said mammal an amount of a formulation, as claimed in any one of claims 1, 49, 75 or 66, effective to induce or maintain anesthesia.

- 74. (Previously Presented) A multi-use container, comprising the formulation as claimed in any one of claims 1, 49, 66, or 75.
- 75. (Previously Presented) A formulation comprising an injectable anesthetic solution, including citric acid and an antimicrobial agent as optional components, said formulation including no more than 15% (weight/volume grams/100 ml) excipients and consisting essentially of, in addition to said optional components, a clear aqueous composition selected from the group consisting of:
 - a) 1% propofol, 9% poloxamer 188, 2% PEG 400, and water;
- b) 1% propofol, 8% poloxamer 188, 4% PEG 400, and water;
 - c) 1% propofol, 8% poloxamer 188, 4% PEG 400, 1% propylene glycol, and water;
 - d) 1% propofol, 8% poloxamer 188, 3% PEG 400, and water;
- e) 1% propofol, 8% poloxamer 188, 3% PEG 400, 1% propylene glycol, and water;
- f) 1% propofol, 7% poloxamer 188, 4% PEG 400, and water; and
- g) 1% propofol, 7% poloxamer 188, 4% PEG 400, 1% propylene glycol, and water, wherein said formulation includes less than 1% lipids.
- 76. (Previously Presented) The formulation of claims 1 or 49 wherein said pH modifiers are selected from the group consisting of sodium hydroxide, potassium hydroxide, and hydrochloric acid.
- 77. (Previously Presented) An aqueous formulation consisting essentially of:
- a) 2,6-diisopropylphenol; and
- b) water; and

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c) up to 15% excipients, wherein said excipients consist essentially of, on a gram per 100 mL total formulation basis, 8% poloxamer 188, 3% polyethylene glycol 400, 1% propylene glycol, 0.2% citric acid monohydrate, a preservative, and sodium hydroxide, and wherein said formulation is clear to the naked eye and includes less than 1% lipids.

78. (Previously Presented) The formulation of any of claims 1, 49, 66, 71, 75, or 77 having an average particle size of from 30 to 75 nanometers.